

PART IX.
510(k) SUMMARY

FEB - 2 2004

In response to the requirements addressed by the Safe Medical Devices Act (SMDA) of 1990, a summary follows with the safety and effectiveness information upon which the substantial equivalence determination is based.

510(k) SUMMARY
for
Aquify Multi-Purpose Solution

1. **Submitter Information**
CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia 30097
Contact Person: Steven Dowdley
Telephone No. 678-415-3897
2. **Device Name**
Classification Name: Soft (hydrophilic) Contact Lens Solution
Proprietary Name: AQUIFY Multi-purpose Solution
3. **Predicate Device(s)**
Aquify Multi-purpose Solution (KARATS Multi-purpose Solution) - K 021635
4. **Description of the Device**
Aquify Multi-Purpose Solution is a sterile aqueous solution containing sorbitol, tromethamine, pluronic F127, sodium phosphate dihydrogen, dextranthenol, edetate disodium dihydrate and preserved with polyhexanide 0.0001.
5. **Indications for Use**
Aquify Multi-Purpose Solution is indicated for cleaning, rinsing, chemical (not heat) disinfecting, storing for soft (hydrophilic) lenses (including silicone hydrogel lenses) as recommended by your eye care practitioner. Aquify Multi-Purpose Solution is also indicated for daily protein removal of lenses replaced in 30 days or less.
6. **Description of Safety and Substantial Equivalence**
A series of preclinical and clinical studies have been completed on this product and were previously submitted under submission K021635. The non-clinical and clinical studies were completed to demonstrate the substantial equivalence of AQUIFY MPS to other currently marketed solutions. All testing was conducted in accordance with and in conformance to applicable device regulations. Results demonstrate the solution is non-toxic and biocompatible, and is comparable to other currently marketed soft contact lens solutions.

In Vitro Cleaning Efficacy

Results of the study showed that Aquify MPS is substantially equivalent to currently marketed products in terms of daily protein removal. This data was previously submitted and reviewed in original 510(k) submission - K021635.

Enzyme Compatibility

The study was conducted to evaluate the proteolytic activity of Unizyme tablets in Aquify MPS (KARATS - 257), SOLOcare Plus and ReNu Multiplus lens care solutions. The results demonstrated that Unizyme tablets dissolved in either Aquify MPS was substantially equivalent to other multi-purpose solution when used as a diluents.

Cytotoxicity

A series of cytotoxicity studies were previously conducted to demonstrate the safety of AQUify MPS. Results of the testing demonstrated that AQUify MPS is non-cytotoxic and is a non-irritant. This data was previously submitted and reviewed in original 510(k) submission - K021635.

Microbiological

Two series of microbiological studies were conducted to demonstrate the microbial efficacy AQUify Multi-Purpose Solution. For the regimen evaluated, the product met both the secondary stand alone criteria and the regimen test criteria for disinfection efficacy.

Clinical Testing

A series of clinical studies have been conducted, submitted and reviewed in 510(k) submission K021635. Data from the clinical studies supported the substantial equivalence of AQUify Multi-Purpose Solution.

7. Substantial Equivalence

The data provided in this 510(k) submission concludes that AQUify Multi-Purpose Solution is substantially equivalent to currently cleared KARATS Multi-Purpose Solution for cleaning, rinsing, chemical (not heat) disinfecting, storing and daily protein removal (when used for lenses replace in and storing soft (hydrophilic) lenses (including silicone hydrogel lenses) as recommended by your eye care practitioner.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

CIBA Vision Corporation
c/o Steven Dowdley
11460 Johns Creek Pkwy.
Duluth, GA 30097

FEB - 2 2004

Re: K033608
Trade/Device Name: AQuify Multi-Purpose Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care
Regulatory Class: Class II
Product Code: LPN
Dated: January 6, 2004
Received: January 7, 2004

Dear Mr. Dowdley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink that reads "A. Ralph Rosenthal". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic and Ear,

Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

PART III. INDICATIONS FOR USE STATEMENT

510(k) Number: (Number to be assigned) K033608

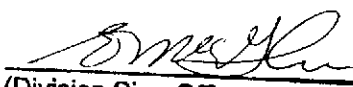
Device Name: AQuify Multi-Purpose Solution

Indications for Use:

AQuify Multi-Purpose Solution is indicated for cleaning, rinsing, chemical (not heat) disinfecting, storing for soft (hydrophilic) lenses (including silicone hydrogel lenses) as recommended by your eye care practitioner. AQuify Multi-purpose Solution is also indicated for daily protein removal of lenses replaced in 30 days or less.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ☐ or over-the-counter: ☒


(Division Sign-Off)

Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K033608